

K960 418

**510(k) Summary of
Safety and Effectiveness**

- 1. Manufacturer/ Submitter**
Marquette Electronics, Inc.
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Milwaukee, WI 53223 U.S.A.

OCT - 2 1996

Establishment Registration Number: 2124823

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Date: October 1, 1996

2. General Information

Common/ Usual Name

This device is commonly known as a patient monitoring system.

Trade/ Proprietary Name

Marquette Electronics, Inc's trade/ proprietary name for this device is the Eagle 3000 Patient Monitor.

Classification Name(s)

The Marquette Eagle 3000 Patient Monitor's classification names, classification panels, and regulation citations include:

- | | | |
|-------------------|---|-------|
| * 21 CFR 870.1025 | Arrhythmia detector and alarm | 74DSI |
| * 21 CFR 870.1110 | Monitor, Blood Pressure, Indwelling | 74CAA |
| * 21 CFR 870.1130 | Monitor, Blood Pressure, Non-Indwelling | 74BXD |
| * 21 CFR 880.2910 | Monitor, Temperature (with probe) | 80BWX |
| * 21 CFR 870.2300 | Monitor, Cardiac (Incl. cardiometer & rate alarm) | 74DRT |

Device Classification

Devices monitoring similar parameters have been determined to be Class II or III devices according to the Cardiovascular Device Classification Panel. FDA has determined this to be a Class III device.

Performance Standards

Performance standards (Section 514 of the Act) have not yet been established for the device that is the subject of this premarket notification submission.

3. Legally Marketed Predicate Device(s)

The Marquette Eagle 3000 Patient Monitor is substantially equivalent, with similar indications for use to the following devices which are currently legally marketed and in commercial distribution:

Marquette Eagle Monitor	K920790
Eagle 3000 Patient Monitor	K952474

4. Device Description

The Marquette Eagle 3000 Patient Monitor is a patient monitoring system that is designed to be used to monitor a patient's basic physiological parameters including: electrocardiography (ECG), invasive blood pressure, non-invasive blood pressure, temperature, and arrhythmia analysis.

The Eagle 3000 Patient Monitor is a factory configured or fixed-parameter patient monitoring device.

Options which allow for the monitoring of invasive blood pressure and the printing of information by a paper recorder may be added to the basic monitor configuration at the factory prior to shipment to the customer.

The Eagle 3000 Patient Monitor has **NOT** been designed as a modular patient monitoring device which allows the addition and deletion of monitoring parameters at the point-of-use.

The Eagle 3000 Patient Monitor has **NOT** been designed as a transport monitor. Therefore, no battery power feature or option has been included with this device.

5. Intended Use

The Marquette Eagle 3000 Patient Monitor is designed to monitor and display patient data. Its design allows the operator to adjust parameter alarm settings that would audibly and visually notify the operator when a violation occurs.

The option is provided for the printing of information by a paper recorder.

Use of the Marquette Eagle 3000 Patient Monitor is intended for patient populations including: adult, pediatric, and/ or neonatal.

Use of the Marquette Eagle 3000 Patient Monitor is not recommended for use in patient's home or residence, during patient transport, or when it has not been ordered by a physician or other qualified medical personnel.

Use of the Marquette Eagle 3000 Patient Monitor is intended for operating room (OR), post anesthesia recovery, critical care, surgical intensive care, respiratory intensive care, coronary care, medical intensive care, pediatric intensive care, or neonatal intensive care. These departments are typically located in hospitals or may be located in outpatient clinics or free standing surgical centers. It is intended for use by physicians, physician assistants, registered nurses, certified registered nurse anesthetists, or other hospital personnel trained in the use of the equipment.

6. Conclusion

Comparative testing was done on the Eagle 3000 Patient Monitor and its predicate devices. Precision and accuracy testing was also performed. Test results indicate that the Eagle 3000 Patient Monitor provides an equivalent level or better in performance, when compared to the legally marketed predicate devices when tested to the accuracy requirements as specified in the contents of the premarket notification submission.

Marquette Electronics, Inc. has demonstrated that the Eagle 3000 Patient Monitor is as safe and effective, and performs substantially equivalent to the predicate devices.